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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,410	06/21/2002	Peter Eriksson	59760 (47137)	2145

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EXAMINER	
GARVEY, TARA L	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,410	ERIKSSON ET AL.	
	Examiner	Art Unit	
	Tara L Garvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-10,12-15,17 and 19-30* is/are rejected.

7)☒ Claim(s) *6, 11, 16, 18, and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/21/2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/18/02, 10/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-33 are pending.

Claim Objections

Claims 6, 11, 16, 18 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claim 30, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 9, 10, 13 and 17 rejected under 35 U.S.C. 102(b) as being anticipated by Chiu et al (Science, 1999, volume 283, pages 1892-1895).

Claim 1 is drawn to a method of selective electrofusion of at least two fusion partners having cell-like membranes by bringing the partners in contact with each other and using a positionable microelectrode to provide the electrical current for fusion. Claim 3 limits the invention of claim 1 to using two microelectrodes that are small enough to provide the selective fusion of two partners. Claims 9, 10, 13 and 17 limit the invention of claim 1 to a microelectrode with diameter of 1-100 μm, to using optical trapping to bring the partners in contact with each other and to the partners being in a buffer prior to fusion.

Chiu et al teaches an electrofusion method for fusing lipid vesicles, which reads on cell-like structures using two small electrodes (5 μm in diameter) that are controlled by micromanipulators. In addition, they teach that the vesicles are transferred to a coverslip on a stage of a microscope, provided in a solution and positioned in proximity to each other prior to fusion by optical trapping (abstract, page 1892, figure1 and third column, lines 7-24 and page 1893, third column, lines 9-18). Thus, Chiu et al teach all that is recited in the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 9, 10, 12-15, 17, 19, 21 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiu et al (Science, 1999, volume 283, pages 1892-1895) in view of Prather et al (US 4,994,384), Tanaka et al (US 4,894,343), Walters et al (US 6,010,613), Chang et al (US 4,970,154), Kranz et al (Sex Plant Reproduction, 1991, volume 4, pages 12-16), Steenbakkers, PGA (US 6,020,170), Walker et al (US 6,041,252) and Heller et al (US 5,827,736).

Chiu et al teaches an electrofusion method for fusing lipid vesicles, which reads on cell-like structures using two small electrodes (5 μm in diameter) that are controlled by micromanipulators. In addition, they teach that the vesicles are transferred to a coverslip on a stage of a microscope, provided in a solution and positioned in proximity to each other prior to fusion by optical trapping (abstract, page 1892, figure1 and third column, lines 7-24 and page 1893, third column, lines 9-18). Chiu et al do not teach the

two fusion partners being a cell and a cell-like structure, using electrodes or micropipettes to contact the cell-like structures prior to fusion, treating the fusion partners with electroporation or dielectrophoresis, or various applications of electrofusion.

Prather et al disclose using electrofusion for the cloning of an animal (column 3, lines 24-47) and micromanipulating the cells using a cell holding pipette with an outer diameter of 120 μm and inner diameter of 25-25 μm, which reads on a micropipette (column 4, lines 24-29).

Tanaka et al disclose that cells are brought in contact with each other using electrodes prior to the electrofusion of two cells (column 4, lines 49-58).

Chang et al disclose dielectrophoresis of cells prior to electrofusion (column 10, lines 50-54).

Kranz et al disclose using electrofusion for the in vitro fertilization of maize in which a single sperm and egg cell were utilized (abstract, page 13, right column, first paragraph).

Steenbakkers, PGA disclose using electrofusion to produce hybridomas for antibody production (column 3, lines 53-58 and column 6, lines 66-67 bridging column 7, lines 1-22)

Walker et al disclose the electrofusion of a cell and a liposome in which the liposome delivers a drug to a cell. For example, electrofusion is used to deliver drugs to the cells of a brain tumor, which reads on a treatment for tumors and a cellular network (column 3, lines 16-23 and 52-55 and column 6, lines 43-48).

Walters et al disclose using electrofusion to deliver drugs into cells, for production of hybridomas and for cancer therapy (column 1, lines 45-57).

Heller et al demonstrated using electroporation to treat a neurodegenerative disorder such as Parkinson's disease (column 3, lines 19-24, column 4, lines 23-27, 31-31 and 54-67 bridging column 5, lines 1-10 and column 6, lines 44-45 and 48-53).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Chiu et al to use other manipulation techniques such as electrodes, pipettes and dielectrophoresis prior to electrofusion, to use different combinations of cell-like structures, and to use electrofusion for various applications because Chiu et al teach that cell-like structures can be positioned prior to electrofusion by optical trapping and Prather et al, Tanaka et al, Chang et al and Walker et al demonstrate that the cells or cell-like structures can be manipulated prior to electrofusion by a pipette, electrodes, electroporation and dielectrophoresis. Furthermore, Kranz et al, Prather et al, Steenbakkers, PGA, Walker et al, Walters et al and Heller et al demonstrate that electrofusion can be used for a variety of applications such as cloning, in vitro fertilization, hybridoma production, delivery of drugs and treatment of diseases.

One would have been motivated to do so to receive the expected benefit, as suggested by Chiu et al and actually exemplified by Tanaka et al, Chang et al, Kranz et al, Prather et al, Steenbakkers, PGA, Walker et al, Walters et al and Heller et al, of being able to manipulate the cell or cell-like structures by various methods prior to electrofusion to achieve the desired outcome of fusion of the structures and to use electrofusion for various applications. Absent of any evidence to the contrary, there

would have been reasonable expectation of success in manipulation of the cells or cell-like structures prior to electrofusion since this has been shown to increase the likelihood of fusion and in using electrofusion for various applications since electrofusion has worked previously for these techniques.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-10, 12, 15, 17, 21-28 and 31-32 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 17-20, 22, 24, 26, 28, 30, 32-34, 37, 39-40, 54, 56, 58, 64, 66, 68 and 70 of copending Application No. 09/996,559. Although the conflicting claims are not identical they are not patentably distinct from each other because the examined claims are anticipated by, or would have been obvious over the claims in Application No. 09/996,559 (US 2003/0104588 A1). The claims of both applications recite a method of fusing cells or cell-like structures using microelectrodes that can be positioned and are

small enough to allow selective fusion of the structures. In addition, both sets of claims recite limitations of at least one microelectrode that is movably mounted on a microchip, hollow, filled with an electrolyte and the outer diameter is no larger than 100 μm. The cell or cell-like structures are in a buffer and exposed to a dielectrophoretic field or a fusogeneic agent prior to fusion. The method of fusing the structures can be used for in vitro fertilization, cloning, cell transfection, preparation of hybridomas, manipulation of cellular membranes or delivery of a defined volume of a substance or a pharmaceutically active substance.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey
Examiner
Art Unit 1636

JAMES KETTER
PRIMARY EXAMINER

TLG